## Nagy, Julia

**From:** Schonfeld, Toby

**Sent:** Wednesday, July 06, 2016 9:33 AM

To: Nagy, Julia

**Subject:** RE: FWA Definition Question

Thanks!

From: Nagy, Julia

Sent: Wednesday, July 06, 2016 9:32 AM

To: Schonfeld, Toby <Schonfeld.Toby@epa.gov>

Subject: RE: FWA Definition Question

Hi Toby,

Manisha and I both updated the internet/intranet sites to reflect the new language.

Julia

From: Schonfeld, Toby

Sent: Wednesday, July 06, 2016 8:24 AM
To: Nagy, Julia < Nagy. Julia@epa.gov >
Subject: RE: FWA Definition Question

Hello.

So let's change the internet/intranet language to the following:

EPA holds a Federal-Wide Assurance (FWA), which is an assurance of compliance that that commits the EPA to complying with the regulatory requirements and upholding ethical principles in conducting human subjects research. This assurance covers all Agency components and therefore provides a basis for the participation of EPA personnel anywhere in the Agency in HSR under conditions that are compliant with applicable regulations.

And the definition you list below is just fine.

Thanks!

Toby

From: Nagy, Julia

Sent: Tuesday, July 05, 2016 10:56 AM

To: Schonfeld, Toby <Schonfeld.Toby@epa.gov>

Subject: FWA Definition Question

Hi Toby,

Is this definition okay for the SOP glossary? Dan and you agreed on this definition for the FAQ but wanted to make sure the same is good for the SOPs.

Federal Wide Assurance (FWA) is an assurance of compliance that commits the EPA to complying with the regulatory requirements and upholding ethical principles in conducting human subjects research.

Also I have a note to remind you to look at the FWA section on the internet site because that is where I originally got the language for the SOP/FAQ and you and Dan wanted to edit it (it's on the 4<sup>th</sup> tab down): <a href="https://www.epa.gov/osa/basic-information-about-human-subjects-research-0">https://www.epa.gov/osa/basic-information-about-human-subjects-research-0</a>

The same one is on the intranet too: <a href="http://intranet.ord.epa.gov/p2/hsr/h">http://intranet.ord.epa.gov/p2/hsr/h</a>uman-subjects-research-regulations-policies

Let me know what you think. Happy to stop by if you want to chat about it.

Thanks,

JULIA M. NAGY Nagy.Julia@epa.gov (202) 564-5152

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